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10/506,682	12/22/2004	Bernard Mariotti	P25917	3415

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EXAMINER	
JOYNER, KEVIN	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/506,682	MARIOTTI ET AL.	
	Examiner	Art Unit	
	KEVIN C. JOYNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-39* is/are pending in the application.

4a) Of the above claim(s) *35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 20-34 in the reply filed on July 21, 2008 is acknowledged. The traversal is on the ground(s) that the Applicant's note that the Examiner's explanation fails to identify one of the two criteria for a proper restriction requirement as set forth in MPEP 803 concerning a serious burden. This is not found persuasive because the instant application is a was filed under 35 U.S.C. 371 wherein special international provisions regarding Unity of Invention pertain as set forth in PCT Rules 13.1 and 13.2. As such, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 35-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 21, 2008.

Claim Objections

3. Claim 20 is objected to because of the following informalities: It appears as though "of" is omitted between the words "one" and "the" in line 15 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21 and 30 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

6. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Regarding claim 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8. Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 30 recites the limitation "the air and water channels" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 31 recites the limitation "the injectors" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeifer (U.S. Patent No. 5,738,824) in view of Graf (U.S. Patent No. 5,494,530).

Pfeifer discloses a process for measuring and controlling the circulation of fluids in endoscope channels comprising;

Placing at least one endoscope into a tank (40);

Coupling one or more inlet channels of the endoscope to a chamber (47) having a known volume and one or more valves (57) as shown in figure 3;

Filling the chamber and valves to a high level position, thereby saturating the tank and inlet channels with a fluid from at least one fluid supply (column 8, lines 55-68);

Controlling and recording a time for fluid flow under pressure within the chamber to travel from the high level position to a designated low level position when at least one of the valves is open to at least a respective one of the one or more inlet channels (column 9, lines 1-42; column 3, lines 19-62; column 4, lines 1-10); and

Confirming that the fluids are circulating in each portion of each channel of the endoscope (column 9, lines 20-40), that the at least respective one of the one or more inlet channels are properly coupled to the at least one of the valves, and that none of the respective one or more channels are closed (column 3, lines 51-63). More specifically, the penetrability and throughput tests of Pfeifer determines that the endoscope channels are properly flushable by measuring the pressure of the apparatus while a fluid is circulated through said channel as well as measuring the amount of fluid circulating through said channel over a certain period of time (column 10, lines 30-68; column 11, lines 1-8). As such this test determines that the channels are properly coupled and that the channels are not closed (otherwise, an improper reading would be measured that would signify that either the channels were closed or the channels were not properly coupled. Therefore, the limitations are met by Pfeifer. Although the method of Pfeifer is under pressure at various times throughout the application, Pfeifer does not appear to specifically disclose that the chamber is specifically a hermetic chamber. Graf discloses a method of measuring and controlling the circulation of fluids in endoscope channels comprising coupling one or more inlet channels of the endoscope to a hermetic chamber and controlling and recording the fluids flowing through the channels of the chamber in order to determine that the channels are properly coupled and the none of the channels are closed (column 2, lines 57-68; column 3, lines 1-10; column 4, lines 38-68). The hermetic chamber is provided in order to produce an airtight assembly in order to determine if leaks exist throughout the apparatus (column 2, lines 11-30). Thus, it would have been obvious to one of ordinary

skill in the art at the time of the invention to utilize a hermetic chamber in the process of Pfeifer in order to produce an airtight assembly for determining if leaks exist throughout the apparatus as exemplified by Graf.

Concerning claim 21, Pfeifer also discloses that the controlling occurs in a controller comprising a plurality of sensors (46 and 55) arranged to detect the emptying of the chamber (column 9, lines 20-35), and an air compressor (54) is structured and arranged to place the fluid under pressure in the hermetic chamber (column 11, lines 10-15), and wherein the controller verifies the known fluid volume and flow rate from a recorded emptying of the hermetic chamber, and uses the recorded fluid volume and flow rate in the confirming (column 9, lines 1-35). Pfeifer does not appear to disclose that the air is filtered. However, it is extremely well known and common to one of ordinary skill in the art to provide filtered air in a method and device of Pfeifer in order to eliminate particulates that may clog the channels and conduits of the system. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Pfeifer to provide filtered air in the apparatus in order to eliminate particulates that may clog the channels and conduits of the system, as such is extremely well known and thus common to one of ordinary skill in the art.

With regard to claim 22, Pfeifer continues to disclose that the controlling and filling of the hermetic chamber comprises emptying of the hermetic chamber down to the low level under pressure, wherein a controller controls a filling time in the filling of the chamber up to the high level ensuring the valves, tank and channels of the endoscope are saturated with fluid; and emptying of the filled hermetic chamber and

recording the time for the fluid to reach the low level (column 5, lines 40-68; column 9, lines 1-20). More specifically, chamber (47) of Pfeifer is utilized to flow a pressurized fluid through the endoscope channels, wherein during startup the chamber is emptied to allow the fluid to enter said valves and channels. After the chamber is emptied, which saturates the valves (57), the channels of the endoscope (20), the tank (40), and the valve (40) is opened and throughput device (46) controls the filling time of the fluid to refill said chamber (47). Therefore, the limitations are met with respect to Pfeifer. With regard to claim 23, Pfeifer also discloses that the controller compares the recorded emptying time of the fluid from the high level to the low level in the chamber to a reference time corresponding to an average time for emptying the chamber under the same pressure through the channel of an endoscope of the same type (column 10, lines 30-68). Concerning claim 24, Pfeifer also discloses that a reference time is recorded in an external database connected to the controller so as to establish a control time (column 9, lines 20-35). With regard to claim 26, Pfeifer also discloses that the control time is undertaken in one or more steps of the fluid cycle (column 3, lines 15-29).

Concerning claim 25, Pfeifer does not disclose that the control time is repeated several times in a same channel of interest, such that an average of the measurements are compared to an independent reference time. Nonetheless, Graf discloses this limitation in column 4, lines 55-60 wherein a repetition of measurements are repeated and analyzed with an independent reference time in order to compare an average of the measurements with the reference time. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pfeifer with Graf such that a

repetition of measurements are repeated and analyzed with an independent reference time in order to compare an average of the measurements with the reference time as exemplified by Graf.

With regard to claim 27, Pfeifer does not appear to disclose that the chamber is purged to verify the impermeability of the hermetic chamber and the one or more channel valves coupled thereto, or pressurizing the hermetic chamber at a given pressure via the air compressor under control of a sensor; such that a recorded measuring of a pressure drop during a specified period of time is sufficient to diagnose leakage. However, Graf continues to disclose purging the hermetic chamber and the one or more valves to verify the impermeability of the hermetic chamber and the one or more channel valves coupled thereto, as well as pressurizing the hermetic chamber at a given pressure via the air compressor (47) under control of a sensor; such that a recorded measuring of a pressure drop during a specified period of time is sufficient to diagnose leakage (column 4, lines 38-68; column 5, lines 1-15). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Pfeifer to include purging the hermetic chamber and the one or more valves to verify the impermeability of the hermetic chamber and the one or more channel valves coupled thereto, as well as pressurizing the hermetic chamber at a given pressure via the air compressor under control of a sensor; such that a recorded measuring of a pressure drop during a specified period of time is sufficient to diagnose leakage in order to detect said leakage as exemplified by Graf.

Concerning claim 28, Pfeifer continues to disclose that the operability of at least one sensor of the chamber is tested (46), wherein the measuring of time for filling the chamber between the low and high levels is recorded, such that said recorded time is compared to an independent reference time (column 10, lines 30-68). More specifically, the sensor is tested when it measures the throughput of fluid into the chamber. With regard to claim 29, an error message is generated when the recorded time is greater or less than the independent reference time in the method of Pfeifer (column 9, lines 35-41).

Concerning claim 30, while Pfeifer discloses that the inlet channels of the endoscope are coupled to valves with connectors (as shown in Figure 3), Pfeifer does not appear to disclose the specifics of the inlet channels in the endoscopes. However, Graf continues to disclose that the inlet channels of the endoscope are coupled to valves with connectors (Figures 2 and 3), one or more separators are positioned and arranged at the inlet channels common to the air and water channels, so as to separate the flows of the air and water of an insufflation piston of the endoscope (Figure 3) wherein the separators allows a very slight communication between the air and the water channels preventing not greater than a 30% loss of flow for each of the channels, such that each of the channels of the endoscope are individually coupled to at least one individual injector located in the tank, a long with being coupled to the hermetic chamber via at least one valve (column 3, lines 52-68; column 4, lines 1-35). The configuration is provided in order to allow the optical portion of said endoscope to remain essentially dry from various liquids that enter the inlet channels of said endoscope. Thus, it would

have been obvious to one of ordinary skill in the art at the time of the invention to provide an endoscope in the method of Pfeifer with the configuration of Graf as set forth above in order to allow the optical portion of said endoscope to remain essentially dry from various liquids that enter the inlet channels of said endoscope as exemplified by Graf. Concerning claim 31, Pfeifer also discloses that the injectors of the tank are coupled to a tube such that one end is free as shown in figure 1. However, Claim 31 further requires that the inner cross section of the tube is less than 5 mm wherein Pfeifer does not disclose this limitation. Nonetheless, it would have been well within the purview of one of ordinary skill in the art to optimize the size of the tube in order to maximize the flowrate of the fluid throughout the tube and the connection of the tube with the injector. Only the expected results would be attained.

With regard to claim 32, the reference continues to disclose that the endoscopes are coupled to the injectors by sealing couplings; the sealing couplings provide fluid flow to pass only when the sealing couplings are properly connected to the inlet of the endoscope channel (column 8, lines 35-50). More specifically, the connections as shown in Figure 1 of Pfeifer are coupled with valve seals that only allow fluid to pass through when the connections are properly coupled via the control device. Concerning claim 33, Pfeifer discloses that the controller is **able** to control at the same time, the flow of several endoscopes using a plurality of hermetic chambers that have different volumes, as well as to increase the control of flow in sets of channels of the same endoscope having similar diameters. More specifically, the controller is programmed to adjust for various volumes of the chambers as well as various diameters of the channels

in the endoscopes. This ability to adjust for these variables discloses that the controller is in fact **able** to control the method limitations as set forth in claim 33.

Concerning claim 34, Pfeifer does not disclose that the method comprises gathering at least one sample solution, wherein the endoscope channels are not disconnected at the end of the disinfecting cycle, and after selecting to open one or more injection valves, the sampling solution is injected through the connection valve using a pump, such that the sampling solution is injected through the one or more channels of the endoscope, of which the sampling solution is then collected at the end of the one or more channels end. Graf continues to disclose that the method further comprises gathering at least one sample solution, wherein the endoscope channels are not disconnected at the end of the disinfecting cycle, and after selecting to open one or more injection valves, the sampling solution is injected through the connection valve using a pump, such that the sampling solution is injected through the one or more channels of the endoscope, of which the sampling solution is then collected at the end of the one or more channels end (column 4, lines 38-68; column 5, lines 1-48). The method of Graf comprises multiple cleaning stages in order to ensure sterility wherein the previous disclosure as set forth above (with respect to claim 34) is provided in order to ensure that the system or endoscope does not produce a leak during the previous cleaning stage. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Pfeifer to include gathering at least one sample solution, wherein the endoscope channels are not disconnected at the end of the disinfecting cycle, and after selecting to open one or more injection valves, the

sampling solution is injected through the connection valve using a pump, such that the sampling solution is injected through the one or more channels of the endoscope, of which the sampling solution is then collected at the end of the one or more channels end in order to ensure sterility as well as to ensure a leak has not produced during subsequent cleaning stages as exemplified by Graf.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

KCJ